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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,395	04/03/2001	Paul G. Alchas	P-4498C1	2608

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EXAMINER	
MENDEZ, MANUEL A	
ART UNIT	PAPER NUMBER
3763	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/825,395	ALCHAS, PAUL G.	
	Examiner	Art Unit	
	Manuel A. Mendez	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/19/2008 (RCE)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/19/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 15, 32, and 38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Hubbard** et al. (US 5505694; hereafter Hubbard).

Hubbard teaches an assembly for use of intradermally injecting medication including hub portion 48 and 50 or 64 and 66 that is able to be attached to a container for storing medication, a needle 52 or 68 supported by the hub portion, the needle having a hallow body and a forward end extending away from the hub portion, and a limiter portion 56 or 72 that surrounds the needle and extends away from the hub portion, the limiter portion generally has a fiat skin engaging surface that is generally perpendicular to the needle, the needle extends forward beyond the limiter portion in a range between 0.5 to 6.0 mm, depending on the desired site of the injection. Specifically, Hubbard teaches that skin thickness, which appears to include the epidermis, the dermis, and the subcutanea layers from Figure 15 (see the description of Figure 15 that states it shows the skin layers penetrated and Figure 15 that shows the subcutanea layer being penetrated by the needle), varies from 0.5 to 6 mm, Hubbard also teaches that the needle length may vary within this range to deposit the medication in epidermis layer, the dermis layer, the tela subcutanea layer or between any of these layers (see Figure 15 and column 8 lines 38-48). See also Figures 2, 15, and 8-11, column 2 lines 7-9, column 3, lines 13-40, column 4 lines 40-49, column 5 lines 21-25, column 5 line 53 to column 6 line 4, column 6, lines 15-26, and column 8 lines 20-67. In addition, Hubbard teaches that the assembly can be used for "injecting any liquid" (column 6 lines 54-58). Therefore, the assembly of Hubbard can be used for injecting vaccines.

As mentioned above, Hubbard teaches the range of 0.5 to 6.0 mm for the range of skin thickness and for altering the extension of the needle beyond the skin engaging surface according to the injection site to deposit the medication in the desired layer (e.g., the dermis layer). Accordingly, Hubbard implicitly teaches that the needle extends beyond the skin engaging surface in the range of approximately 0.5 to approximately 6 mm. Since this range completely encompasses the claimed range of approximately 0.5 to approximately 3 mm with sufficient specificity (e.g., altering the extension of the needle beyond the skin engaging surface according to the injection site to deposit the medication in the desired layer), it anticipates the range of approximately 0.5 to approximately 3.0 mm as claimed. When the prior art discloses a range that touches or overlaps the claimed range, but no specific examples falling within the claimed range are disclosed, a case-by-case determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. In this case, Hubbard clearly teaches limiting the needle extension so that the injection is deposited in the dermis layer (like the claimed invention) and that the thickness of the dermis layer varies dependent on the patient's age, weight, anatomical site of the injection, and other factors (see column 3 lines 25-40 and column 8 lines 39-43). One of ordinary skill in the art would know that the dermis layer generally begins at 0.5mm below the skin outer surface (e.g., below the epidermis), and that the dermis layer is between the epidermis and subcutanae layers, which is the farthest layer. Accordingly, given these factual teachings, Hubbard anticipates the claimed range to approximately 0.5 to approximately 3 mm.

A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, as it does here, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Further, a recitation of the intended use (e.g., for use in ... injecting vaccines) or function of the claimed invention must result in a structural

difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the claimed function or intended use, it meets the claim.

Claims 1-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hubbard** et al. (US 5505694; hereafter Hubbard) in view of **Gross** (US 5,848,991), and in further view of "Clinical Do's & Don'ts - Giving Intradermal Injections" by Edwina McConnell, RN, PhD. (hereinafter "**the McConnell article**) and "Substances producing pain and itch" by C.A. Keele et al. (hereinafter "**the Keele article**").

Hubbard teaches the claimed invention, including limiting the needle length to inject medication in the desired skin layer (e.g., the dermis layer). Hubbard does not explicitly teach that the needle extends between "approximately 0.5 to approximately 3 mm" beyond the skin engaging surface. Gross teaches an intradermal drug delivery device that has a needle projecting outwardly from the skin engaging surface in the range of 0.3 to 3 mm in order to "penetrate through the epidermis and into the dermis." (see column 2 lines 18-21 and column 6 lines 34-37). Accordingly, it would have been obvious to one of ordinary skill in the art to use the teachings of Gross as to the desired range of the needle extension for injecting medication into the dermis layer (0.3 to 3 mm) in combination with the broader range taught by Hubbard (0.5 to 6mm for the total thickness of the epidermis, dermis and subcutanea layers), to arrive at the claimed range of approximately 0.5 to approximately 3.0 mm to ensure the medication is injected in the dermis layer.

Additionally, Hubbard teaches the method of injecting any liquid into the skin only in the dermis layer, comprising the steps of pressing a very fine gauge needle perpendicularly into the skin, wherein the needle is in fluid communication with a container having a reservoir; and injecting the liquid into the dermis layer of the skin with the depth penetration of the needle being limited to the intradermal space by a limiter that surrounds the needle and has a generally fiat skin engaging surface. Hubbard does not teach the needle being no greater than 30 gauge. The Keele article teaches the use of very fine needles of 30 gauge in intradermal injections. Hubbard does not teach that the liquid is a vaccine. The McConnell article it is well known in the art to give

vaccines by intradermal injections. Therefore, it would have been obvious to one of ordinary skill in the art that the container could be filled with a vaccine, and to use a very fine needle of no greater than 30 gauge as taught by the Keele and McConnell articles. Finally, Hubbard also teaches that the step of pressing the needle perpendicularly to the skin includes orienting the needle perpendicularly to the skin (column 8 lines 35-36), the step of injecting the liquid including moving the plunger to cause the liquid to be forced out of the reservoir. The McConnell article teaches the liquid can be a vaccine. Additionally, Hubbard teaches filling the container with the liquid, and the McConnell article teaches the liquid can be a vaccine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez
Primary Examiner
Art Unit 3763

MM